Claims

1. Valacyclovir hydrochloride in anhydrous crystalline form having substantially the following d-spacing pattern (in angstroms):

d-spacing
6.76
9.36
11.54
13.98
15.45
15.75
17.12
19.10
21.39
23.02
24.23
26.41
27.46
28.06

2. Valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 1 having substantially the X-ray diffraction pattern of Figure 2.

3. Valacyclovir hydrochloride in anhydrous crystalline form having substantially the characteristic infrared peaks

IR (cm^{-1}): 1686.42, 1572.60, 1533.52.

4. Valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 3 having substantially the characteristic infrared peaks

IR (cm^{-1}): 3377.99, 3285.87, 3197.62, 2930.92, 1749.72, 1686.42, 1631.12, 1607.17, 1572.60, 1533.52, 1476.48, 1364.98, 1298.63, 1258.79, 1248.27, 1225.22, 1132.81, 1097.06, 778.37, 759.33.

5. Valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 3 having substantially the infra-red absorption spectrum of Figure 1.

6. A pharmaceutical composition comprising a valacyclovir hydrochloride form as claimed in claim 1 to 5 along with one or more pharmaceutical carriers/ excipients.

7. Valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 1 to 5 for use in medicine.

8. Use of valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 1 to 5 in the manufacture of a medicament for use as an antiviral agent.

9. A process for the preparation of valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 1 to 5 comprising;

1) mixing valacyclovir hydrochloride hydrate with a substantially pure C_{1-6} lower alcohol solvent and heating the resulting suspension;

2) evaporating the solvent under reduced pressure and isolating the resulting solid.

10. The process of claim 9 wherein said solvent is ethanol.

11. The process of claim 9 or 10 wherein the suspension is heated at between 50 to 70°C for at least 12 hours.

12. The process of claim 11 wherein the suspension is heated at 60°C for 20-21 hours.

13. A process for the preparation of valacyclovir hydrochloride in anhydrous crystalline form as claimed in claim 1 to 5 comprising;

1) mixing valacyclovir hydrochloride hydrate with a substantially pure C_{1-6} lower alcohol solvent and adding the resulting suspension to substantially pure refluxing lower alcohol;

2) distilling off the solvent to form a suspension and maintaining the same at room temperature for at least 8 hours; and

3) isolating the resulting solid.

14. The process of claim 13 wherein the solvent and refluxing lower alcohol are ethanol.

15. The process of claim 13 or 14 wherein approximately one third of the solvent is distilled off to form said suspension.